REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Prior to the present amendment, claims 30-34, 45, 46, 48-50, 73 and 74 were pending and under consideration. By the present amendment, claims 45-50 are canceled, and claims 30 and 73 are amended to more specifically recite certain aspects of the invention. Support for these amendments is provided throughout the specification as filed. Specific support for peptide analogues comprising not more than 20 amino acids is provided, *e.g.,* on page 6, lines 33-34. It should be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 30-34 and 74 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly define the metes and bounds of the claimed invention. More specifically, the Action asserts that the term "*in vivo* proteolysis" is vague and unclear, since the conditions for *in vivo* proteolysis vary widely.

Applicants respectfully traverse this basis of rejection and submit that the skilled artisan would be fully apprised as to the scope of the instant claims, in light of the general knowledge in the art and the teachings of the specification, which explicitly recite that in one aspect, "the peptide analogue additionally has the N-terminal and C-terminal residues altered to an amino acid such that proteolysis is reduced upon administration to a patient as compared to a peptide analogue without these additional alterations." Accordingly, the skilled artisan would appreciate that the proteolysis conditions are the *in vivo* conditions present upon administration to a patient. However, without acquiescence to this basis and to expedite prosecution of the instant application, claim 30 has been amended solely for purposes of clarification to recite that it is the N- terminal and/or C-terminal amino acid of the peptide analogue that is altered such that upon administration *in vivo* proteolysis is reduced. Applicants submit that the skilled artisan would clearly understand the nature of the N-terminal and/or C-terminal alteration, and, in light

of these amendments and remarks. In addition, altering this language could cause further confusion as other members of this patent family namely U.S. Patent Nos. 6,329,499, 6,251,396 and 6,379,670, contain such language. Accordingly, for clarity as well as consistency, Applicants respectfully request that the Examiner reconsider and withdraw this basis of rejection.

Rejections Under 35 U.S.C. § 102

Claims 30-34, 73 and 74 stand rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Bellacosa *et al.* or Pautot *et al.* Specifically, the Action asserts that Bellacosa *et al.* describes a vAkr peptide containing an amino acid sequence at positions 689-697 that reads on the instantly claimed fragments of SEQ ID NO:3 in which Lys 91 is replaced with Ala and N- and C-termini of the fragment are altered. The Action further asserts that Paudot *et al.* teaches peptides containing an amino acid sequence at positions 159-172 that read on peptides of claims 30, 32, and 33 wherein Lys 91 is replaced with Ala and wherein N- and C-termini are modified, in addition to peptides of claim 73 wherein Lys 91 is replaced with Ala and residues in positions 86-90 and 97-99 are also replaced.

Applicants respectfully traverse this basis of rejection and submit that neither reference teaches each element of the instant claims, and, therefore, neither reference anticipates the claimed invention. Specifically, Applicants note that claims 30 and 73 have been amended, without acquiescence to this basis of rejection, to include the feature that the claimed peptide analogues do not comprise more than 20 amino acids. Specific support for peptide analogues comprising not more than 20 amino acids is provided, *e.g.*, on page 6, lines 33-34 of the instant application. The polypeptides described by Bellacosa *et al.* and Pautot *et al.* clearly include more than 20 amino acids and, therefore, do not include this feature of the claimed invention. Furthermore, neither of these references disclose fragments having 20 or fewer amino acids and specifically comprising at least seven consecutive amino acids selected from residues 86 to 99 or human myelin basic protein as recited in SEQ ID NO:3. Accordingly, Applicants submit that neither Bellacosa *et al.* nor Pautot *et al.* anticipate the invention.

Claims 45, 46, 48-50 and 74 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Wucherpfenig *et al.* Specifically, the Action asserts that Wucherpfenig *et*

al. teaches peptide analogs comprising residues 84-102 of MBP with Ala substitutions of one of the residues selected from the residues at positions 86-97 and that analog (85-99)93A reads on instantly claimed peptides wherein Lys-91 is substituted with Ala.

Applicants respectfully traverse this basis of rejection and submit that Wucherpfenig *et al.* fails to teach each element recited in the instant claims and, therefore, fails to anticipate the presently claimed invention. However, without conceding that Wucherpfenig *et al.* was published prior to invention by Applicants and without acquiescence to this basis of rejection, claims 45-50 have been canceled, and claim 74 amended so that it does not depend from claim 45. Applicants submit that this basis of rejection is obviated by this amendment and respectfully request that it be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 31, 33 and 49 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Bellacosa *et al.*, Pautot *et al.*, or Wucherpfenig *et al.* in view of Nishimoto *et al.* In addition to the teachings of the primary references described above, the Action asserts that Nishimoto *et al.* teaches that the replacement of an L-amino acid residue with the corresponding D- isomer is a standard way of rendering the polypeptide less sensitive to proteolysis. Accordingly, the Action concludes that it would have been obvious to an artisan to alter the terminal amino acid residues of MBP polypeptide analogs from L- to D- isomers to reduce proteolysis.

Applicants respectfully traverse this basis of rejection and submit that the claimed invention is non-obvious in light of the references cited above, either alone in the combinations applied, since the references fail to teach each feature of the claimed invention. Without acquiescence to this basis of rejection, claims 49 has been canceled and claim 30, from which claims 31 and 33 depend, has been amended to recite the feature that the claimed peptide analogues comprise not more than 20 amino acids. Applicants submit that neither Bellacosa *et al.*, Pautot *et al.*, nor Wucherpfenig *et al.* teach a peptide analogue comprising at least seven consecutive amino acids from residues 86-99 of human myelin basic protein, wherein the L-lysine at position 91 is altered and the N-terminal and/or C-terminal amino acid are altered, and

wherein the peptide analogue comprises not more than 20 amino acid residues. Furthermore, Nishimoto *et al.* fails to remedy this deficiency, since it does not teach any human myelin basic protein peptide.

Double Patenting Rejections

Claim 34 stands rejected under 35 U.S.C. § 101 for allegedly claiming the same invention as that of claim 7 of prior U.S. Patent No. 6,329,499.

Applicants respectfully traverse this basis of rejection and submit that claim 30, from which claim 34 depends, has been amended without acquiescence to this basis of rejection to recite the feature that the peptide analogue comprises not more than 20 amino acids. Applicants further submit that claim 7 of U.S. Patent No. 6,329,499 fails to include this feature and, accordingly, claims a different invention that instant claim 34. Applicants respectfully request that this basis of rejection be withdrawn.

Claims 30-34, 45, 46, 48-50, 73 and 74 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 2 and 7 of U.S. Patent No. 6,329,499. The Action asserts that the claims are not patentably distinct from each other because the claims of U.S. Patent No. 6,329,499 are drawn to peptides with substituted Lys-91 and, optionally, N- or C- terminal residues (claim 7) or other residues (claims 1 and 2).

Without acquiescence to this basis of rejection, Applicants submit that claim 45-50 have been canceled and claims 30 and 73 amended, to recite the feature that the claimed peptide analogues comprise not more than 20 amino acids. Applicants submit that peptide analogues having this feature are not obvious in light of the claims of U.S. Patent No. 6,329,499, which fail to include this characteristic. In light of this amendment, Applicants respectfully request that this basis of rejection be reconsidered and withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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